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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 08/821,025   | 03/19/1997  | HENDRIK LOUIS BIJL   | 246152006900            | 3574             |
| 25225  | 7590        | 04/04/2006           |                         |                  |
| MORRISON & FOERSTER LLP<br>12531 HIGH BLUFF DRIVE<br>SUITE 100<br>SAN DIEGO, CA 92130-2040 |             |                      | EXAMINER<br>MARX, IRENE |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 1651                    |                  |

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 08/821,025             | BIJL ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Irene Marx             | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 68,72,76-80,83-95 and 113-115 is/are pending in the application.
- 4a) Of the above claim(s) 96 and 113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68,72,76-80,83-95,114 and 115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

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### DETAILED ACTION

The amendment filed 2/23/06 is acknowledged. Claims 68, 72, 76-80, 83-95 and 114-115 are being considered on the merits.

Claims 96 and 113 are withdrawn from consideration as directed to a non-elected invention.

Upon reconsideration, the new matter rejection is no longer maintained.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68, 72, 76-80, 83-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is confusing in that the phrase "granular particles of the extruded microorganisms" fails to find proper antecedent basis.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68, 72, 76-80, 83-95 and 114-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto *et al.* (U.S. Patent No. 4,916,066) taken with Barclay MO(U.S. Patent No. 5,656,319) and Huang *et al.* (U.S. Patent No. 4,056,38) for the reasons as stated in the last Office action and the further reasons below.

Akimoto *et al.* teach a dry *Mortierella* composition (See, e.g., col. 8, lines 7-12). The reference differs from the claimed invention in that the dried composition is not in extruded

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granule form. However, Barclay teaches a related microbial composition containing fatty acids wherein the composition is extruded. See, e.g., bridging paragraph between col. 11 and 12.. The reference recognizes the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion. In addition, Huang *et al.* teach extruded granules of fungi such as *Aspergillus* which are subsequently dried. See, e.g., bridging paragraph between col. 2 and 3, and col. 3, lines 11-17. The extruded material would reasonably be expected to be porous as claimed, to have the degree of dryness required and to have the dimensions as claim designated.

The properties of the dried *Mortierella* as far as oil content and sizing discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of composition properties for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the dried *Mortierella* product of Akimoto *et al.* by submitting the biomass to an extrusion and drying process as disclosed by Barclay and Huang *et al.* in view of the expected economic benefits of obtaining a dried stable microbial product that is easy to manipulate and the cost of which is reduced.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments appear to be directed to a composition consisting of porous extruded *Mortierella*, while claims 68, 72, 76-80, 83-95 are drawn to a composition **consisting essentially of granules comprising** extruded *Mortierella* which have "a porosity" which is "generated by drying granular particles of the extruded microorganisms". Only in dependent claims 91-93 is the porosity claim designated. Claims 114 and 115 are directed to "granules **comprising** extruded microorganisms which are fungi of the genus *Mortierella*, wherein the granules (i) have

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a porosity generated by drying of granular particles of the extruded microorganisms (ii) comprise arachidonic acid and (iii) have an average dry-matter content of 80% or more”.

Applicant's attention is directed to the fact that the amount of *Mortierella* comprised by the composition is not claim designated. Similarly, there is no clear nexus between the polyunsaturated fatty acid touted as being extractable from the granules and any HUFA content in the *Mortierella* fungi.

Applicant argues that there is no motivation to combine the references because none of the references teaches the identical composition as disclosed by the instant application. Yet this is not an anticipation rejection, but rather an obviousness rejection. In addition, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co. Inc, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

Regarding the teachings of Akimoto, the reference discloses dried *Mortierella* cells which are not extruded. However, the arguments directed to efficient extraction techniques are not pertinent to the claimed invention. Contrary to applicant's contentions, Barclay is relied for its teaching of dried cells, although Barclay also does disclose wet cells which are processed by extruding and drying. It is submitted that any and all cells upon cultivation are necessarily wet prior to drying. Barclay teaches a related microbial composition containing fatty acids wherein the composition is extruded and dried See, e.g., bridging paragraph between col. 11 and 12 and col. 33 lines 1-4.

That Barclay speculates that *Mortierella* is not a good commercial source of certain fatty acids is noted. However, this is not seen as teaching against providing an extruded composition comprising dead *Mortierella* cells, particularly since Barclay recognizes that any oil available in fungal mycelia would be more readily extractable upon extruding. This finding strongly suggests that the extruded particles of Barclay have a porosity at least to some extent. With respect to water content, at col. 12 the reference indicates that the water content of less than 40% is desirable in that the extruded particles provide for a greater amount of HUFAs.

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In response to applicant's allegations that there would be no motivation to combine Akimoto and Barclay, it is noted that inasmuch as Akimoto produce a *Mortierella* composition containing oil and demonstrates that *Mortierella* cells are rich in HUFAs, one of ordinary skill in the art would have had a compelling motivation to provide an extruded composition comprising *Mortierella* cells as suggested by the teachings of Barclay for the expected benefit of having a stable and healthful food composition that is valuable for its nutritional value, for example.

In this regard, the intended use in Barclay and in Huang of the extruded composition for animal feed is not seen as preventing its use for the extraction of oil, if so desired. The intended use of the composition does not distinguish the composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. Barclay teaches the extrusion and subsequent drying of fungal mycelia, which is deemed to be applicable to all fungi, of course including *Mortierella*.

Moreover, there is no clear reason provided in the Response to preclude the use of the instant composition as a food additive, for example. See, e.g., Specification, page 19, lines 10-13, wherein this use is specifically disclosed for the dried extruded granules of the invention.

Applicant argues that there is motivation lacking to further dry the extruded fungal composition of Huang after extruding. Yet, it is not clear that the properties of a product produced in the process of Huang differ substantially from the properties of the instant product. There is nothing on the record to suggest that the order of extruding and drying affects the product made. It is noted that the granules claimed as product by process range in size from 0.1 mm to 12 mm. Clearly the product by process as claimed is not uniform at least as far a size is concerned.

In response to the contentions in the Response that the limitations of porosity, degree of dryness and dimensions are not met, it is noted that Barclay specifically suggests that a dryness of less than 40% improves the ease of oil extraction. Thus a degree of dryness of at least 60% is at least suggested.

Inasmuch as the claims require "a porosity" or a lower limit of the range of porosity of 15%, 20% or 25%, one of ordinary skill in the art would reasonably have expected this degree of porosity in an extruded composition comprising mycelia that is subsequently dried. There is no

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reasonably<sup>e</sup> expectation of obtaining a composition that is solidly dense and compact when using the recited processes of making a composition.

The granule size appears to be selected to optimize the product for certain purposes. It is not readily apparent that the size limitation is critical for the properties of the product as touted.

The arguments directed to unexpected results touted starting at page 12 of the Response have been carefully considered. There is no clear indication in the written disclosure as to the nature of the extrudate used in Example 16, and applicant did not indicate the purpose of citing this example with any particularity. As to Example 25, it indicates that the product was produced according to Example 1. In Example 1, fermentation broth of *Mortierella alpina*, previously pasteurised (68° C for 1 hour) (palletized growth) was filtered and the filter wet cake was recovered with a dry matter content of about 25%. Three types of drying procedures were employed. vacuum drying; ventilation tray dryer and fluid bed dryer. The dried material recovered by fluid bed dryer was used for extraction of oil by means of hexane at six different temperatures. Extraction at room temperature gave lower yields; better yields were obtained at elevated temperatures. Thus the relevance of Example 25 is unclear since the product does not appear to have been extruded.

That production of an extrudate enables easy drying is noted. However, the claims are not directed to a process of making a product, but rather to a composition “consisting essentially of granules comprising extruded *Mortierella*” which have “a porosity” which is “generated by drying granular particles of the extruded microorganisms” or “granules comprising extruded microorganisms which are fungi of the genus *Mortierella*, wherein the granules (i) have a porosity generated by drying of granular particles of the extruded microorganisms (ii) comprise arachidonic acid and (iii) have an average dry-matter content of 80% or more”.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

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No claim is allowed.

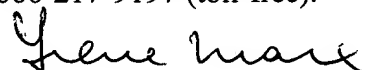
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx  
Primary Examiner  
Art Unit 1651